Responses of Timothy F. Malloy
UCLA Sustainable Technology and Policy Program*
June 13, 2011

In responding to these questions, I am making certain assumptions about the general structure of the regulatory program. The statute is silent as to whether the Department of Toxic Substances Control (DTSC) or individual manufacturers (or consortiums of manufacturers) should perform the alternatives analysis. Likewise, the statute provides no guidance regarding whether alternatives analyses should be manufacturer-specific (regardless of who performs them) or instead be sector-based (i.e., a single, centralized alternatives analysis covering a product produced by numerous entities).

The structural decisions concerning the identity of the responsible entity (private or government) and the scope of the analysis (individual versus sector-based) will have significant implications for the nature of the alternatives analysis process. Prior draft regulations under AB 1879 and discussions at meetings of the Green Ribbon Science Panel suggest that DTSC is thus far treating the alternatives analysis process akin to an individualized permitting program in which individual manufacturers (or groups of manufacturers working voluntarily together) submit AAs to the agency for some type of review and regulatory action. My responses likewise adopt that assumption for the purposes of responding only.

Question #1A: **What basic requirements in an AA for a window cleaner contain that will meet the requirements of HSC section 25253? (What basic requirements should a compliant AA contain and should be set out in the regulations?)**

The regulations should set a default set of requirements for all AA's for formulated products and manufactured goods. In the context of a regulatory program in which the AA is meant to support regulatory responses, the AA should meet five basic principles:

- Protectiveness: The statute charges DTSC to "determine how best to limit exposure or to reduce the level of hazard posed by a chemical of concern." This central principle should guide the crafting of the regulations and the design of the AA process; accordingly, the process should place most emphasis on achieving this goal.

- Consistency: In a regulatory program, similar products should be treated in a similar fashion. Differences in treatment should be linked to well-defined differences in the nature of the product, its production process, or uses. Regulatory responses should not vary as a result of solely private business decisions about the nature, scope or methodology of the AA process selected by the manufacturer.

- Rigor: The AA process should be grounded in science (including decision science), with well articulated standards and methodologies. This principle recognizes, however, that science does not equate with certainty. Decisions will have to be made in the face of uncertain or incomplete data, and in

* Institutional affiliation is provided for identification purposes only.

dealing with such conditions, the AA process should adopt scientifically defensible approaches and assumptions.

- Proportionality: Not every case will present the same level of complexity. The AA process should be flexible enough to scale the intensity of the AA to the needs of the particular case, all the while incorporating the other principles of protectiveness, consistency, rigor, and transparency. The AA process should have a basic default structure, but the scope and nature of components of that structure) should be adjusted were necessary to reflect the complexity of the issues. For example, in many permitting programs, simple, commonly-occurring activities are sometimes dealt with under general permits with reduced application requirements.

- Transparency: The AA methods, process and individual outcomes should be transparent, meaning interested parties should have access to the methods, information, assumptions and data underlying the outcomes. Transparency serves multiple purposes. It reflects normative views about the right of the public to be engaged, pragmatic interests of securing legitimacy for the ultimate outcome, and substantive beliefs that knowledgeable public engagement can improve the outcomes.[1] Transparency does not require that *methods* be simple enough that a lay person without specialized training could evaluate the methods or their application, but rather that engaged, knowledgeable participants could do so.

In terms of the elements of the AA, existing AA approaches and frameworks provide the basic components of the AA: problem formulation (identification of alternatives, data requirements, etc.); data collection; alternatives assessment (systematic assessment of the health and safety, environmental, performance, and economic attributes of the baseline chemical/product and those alternatives); and alternatives evaluation (the weighted balancing of the respective attributes of the baseline chemical/product and the alternatives.)

(i) At a minimum, what should the AA for a window cleaner contain that will meet HSC 25253? Should a basic requirement in the window cleaner AA include consideration or evaluation of whether the chemical of concern is necessary in the product? If not, what? Or are there other basic requirements?

The question of whether the CoC is necessary in the product should be determined as part of the AA process. Presumably, one alternative to be considered may be a formulation of the product without the CoC. In some cases, the manufacturer may

[1] Kheifets, *et. al*, *Risk Governance for Mobile Phones, Power Lines and Emerging Technologies*, 10 Risk Analysis 1481 (2010); National Research Council, PUBLIC PARTICIPATION IN ENVIRONMENTAL ASSESSMENT AND DECISION MAKING (2008).

simply propose to remove the CoC without altering the product in any other way. This may be an appropriate case for a truncated form of AA, although some consideration should be give to the existence of other alternatives that are even safer than the modified product. In other cases, the alternative may substitute another chemical for the CoC. This is the classic type of situation that an AA is intended to address. In both cases, the necessity of the CoC would be considered as part of the performance aspect of the alternatives evaluation.

(ii) What are the minimum steps or procedures (i.e., process) needed in the AA evaluation for the window cleaner that the manufacturer must follow?

See above.

(iii) What pre-screen criteria should be used to decide whether the potential alternatives for the window cleaner should be addressed in the AA? How should the term "availability of potential alternatives" be defined?

As noted above, protectiveness should be the guiding principle for the AA process. Thus, in cases in which a potential alternative presents fairly clear, substantial health or environmental concerns well beyond those of the baseline, it would be appropriate to screen that alternative out in the problem formulation stage. I would be more cautious about screening out potential alternatives based on performance or economic factors as some reduction in performance or increase in cost may ultimately be acceptable in light of the health or environmental benefits of an alternative. This type of balancing is the point of the AA, and thus it would be premature to engage in it as a screening exercise. That said, it may be appropriate to identify some disqualifying standard for performance or cost to account for cases in which a potential alternative simply will not function at all or the costs would be clearly exorbitant.

"Availability" of potential alternatives should look to whether the alternative is or will be commercially available for the use covered by the AA. Technology transfer should be considered here; thus, the fact that an alternative has not been commercially applied to the specific use in question should not disqualify it from consideration if it could be used for that purpose. Likewise, an alternative should not be excluded simply because the capacity to produce or distribute it on the scale required for use is not currently available. AA should be dynamic in nature, considering potential changes that would occur in the future should an alternative be adopted. Regulatory responses can use methods such as gradual phase-in to smooth the transition to an alternative.

(iv) What kind of guidance or requirements should be used to determine the potential alternatives for the window cleaner when evaluating the economic impacts (cost) and performance (product function) factors?

If one assumes a quasi-permitting scenario in which individual businesses perform AAs, then consideration of economic impacts should be limited to the costs/revenues, if any, experienced by the individual firm in adopting an alternative.

Thus, the analysis should not consider the broader impacts on the economy in terms of jobs, business growth, etc. This is consistent with economic cost approaches used in permitting programs generally (such as new source review) and in REACH for the authorization process.[2] The analysis should take the form of a comparative assessment of the net present value of the direct and indirect costs/revenues associated with the baseline and alternative products. Useful examples are set out in the REACH Authorization guidance and EPA's Cleaner Technologies Substitutes Assessment methodology. The analysis should also consider impacts on the price to consumers.

Question #1B: **What are the basic requirements (if any) that would meet the life cycle requirements of HSC section 25253 for the window cleaner? Are the requirements for a window cleaner life cycle assessment satisfied by "life cycle thinking", life cycle inventories, or more full blown life cycle analyses?**

(i) For example, the potential alternatives identified for a window cleaner are: (1) glacial acetic acid and water, (2) household vinegar and water and (3) household ammonia and water. Should each potential alternative undergo a complete full blown life cycle analysis for each of the 13 factors? Or can "life cycle thinking" be used to satisfy all or some of the 13 factors instead of a more full blown life cycle analysis?

The agency should adopt a "life cycle thinking" approach to its evaluation of the 13 factors/criteria set out in Section 25253 (a) (2) (a)-(m) of the statute. Very sophisticated methods for life cycle impact analysis of the health, environmental, performance and economic aspects of baseline products and alternatives exist.[3] Generally speaking, these methods are too complex for use by individual businesses in a regulatory program of this nature. In addition, as currently configured, they do not capture all of the criteria required under the statute.

Question #1C: **Should / how should the window cleaner AA evaluation group the 13 elements specified in HSC section 25253? Should the 13 elements be sequenced or be left entirely to the discretion of the entity performing the AA on window cleaner?**

(i) Should the window cleaner AA be staged so to screen out alternatives as the AA progresses from one stage to the next (see *Attachment 1-2*)? For example, should the AA sequence for the window cleaner be:

Step 1. Group, evaluate and screen out the potential alternatives impacts based on the health and environmental factors.

---

[2] *See* ECHA, GUIDANCE ON THE PREPARATION OF AN APPLICATION FOR AUTHORISATION 74 (January 2011); EPA, CLEANER TECHNOLOGIES SUBSTITUTES ASSESSMENT-- A METHODOLOGY AND RESOURCE GUIDE (EPA/744-R-95-002 Dec. 1996).

[3] *See* for example Xiaoying Zhou and Julie M. Schoenung, *An Integrated Impact Assessment and Weighting Methodology: Evaluation of the Environmental Consequences of Computer Display Technology Substitution*, 83 J. Envt'l Man. 1 (2007); EPA, SOLDERS IN ELECTRONICS: A LIFE CYCLE ASSESSMENT (EPA 744-R-05-001 AUG. 2005).

Step 2. Group, evaluate and screen out the potential alternatives impacts based on the life cycle of the potential alternative.
Step 3. Evaluate product performance, useful life and cost factors for the remaining potential alternatives for window cleaner.

Is this the most effective sequence and is it considered "proportional"?

I believe that the A-M factors (and the other factors in the body of sub-section (a) (2)) should be grouped in the manner set out in Table 1, attached. Generally speaking, as discussed in my response to Question 1A (iii) above, I see value in some threshold screening of alternatives as part of the problem formulation component of AA. However, the "screening" discussed in this question is quite different than what I discuss above. The sequential "screening" here is actually a lexicographic decision analysis approach in which decision criteria are applied sequentially to evaluate a set of alternatives and select a preferred alternative (or set of alternatives.) Those alternatives that meet the health and environmental criteria of Step 1 move on, and so on. This approach is non-compensatory; that is, an alternative that does badly on one criterion cannot "make that up" by doing better on another. As set out here, the approach does appear to stress the principle of protectiveness by making health and environmental concerns the threshold step. A compensatory approach allows the decision-maker to make trade-offs across the different decision criteria or factors.

It is difficult to say whether this is the most "effective" sequence because the structure of the decision-making approach is more a question of preference than effectiveness. A lexicographic approach has certain benefits in terms of simplicity and efficiency (i.e., reducing the amount of data to be collected in certain cases), but it may not identify alternatives presenting the most desired mix of features. Adoption of threshold screening as discussed in response to Question 1A (iii) with a compensatory approach can capture many of the benefits of a lexicographic approach while retaining the compensatory nature of a trade-off analysis.

I would ***not*** leave questions regarding the type of decision approach or the grouping of the factors to the individual firms, as this would likely undermine the principles of consistency and transparency, and ultimately could affect protectiveness.

Also, it appears that the sequence set out in this questions links "life cycle" consideration to only certain of the A-M factors or criteria. I would not use the concept of life cycle in that way. It appears to me that each of the A-M factors or criteria have life cycle implications. For example, consideration of public health impacts under 25253(a) (2) (k) should consider worker impacts through the supply/manufacturing chain, consumer exposures in use, and end of life human health impacts.

(ii) Elements (A) and (B) are properties of an alternative, whereas, elements (C) through (M) are impacts of an alternative. Should the window cleaner AA use the first two elements to screen out

alternatives before, after or simultaneously with consideration of the other elements?

See response to 1A (iii) and 1C (i), above.

Question #1D: **What data or other information should be required or developed and evaluated to support the window cleaner AA analysis?**

(i) What would be the minimum documentation and data requirements to address each of the 13 elements specified in HSC section for the window cleaner AA? Would trade secret data that has been peer reviewed be acceptable (i.e., transparent, rigorous, and consistent)?

Regarding trade secret data, the question of transparency is controlled by the application of Section 25257. It seems to me that some of the data required for the baseline product and alternatives may fall within the statute's definition of trade secrets. In order to maintain transparency, the agency should evaluate claims of trade secret protection very closely and require meaningful, complete and expeditious substantiation. Peer review of trade secret data would enhance its rigor and, assuming the peer review was governed by clear widely accepted standards, its consistency.

(ii) Should the window cleaner AA analysis use tools or instruments that are commonly available, but are proprietary (e.g., fill in the information and the tools/instrument (e.g., model) provides an answer to use for comparison with potential alternatives to the window cleaner)? Would the proprietary models satisfy the following criteria: transparent, rigorous, and consistency?

Generally speaking, the regulatory program could choose one of three approaches: (i) a single, mandatory method or set of methods[4] developed by DTSC, (ii) a *default* mandatory method or set of methods, which can be altered with the approval of DTSC, or (iii) no mandatory method with individual firms having the discretion to choose a method meeting certain standards.

Proprietary methods would fall into the third category, and would have very serious implications for transparency. It is possible that such proprietary methods could be rigorous, although the public (and perhaps even the agency) would have no real basis on which to evaluate that issue. This third category (whether proprietary or not) also raises serious concerns about consistency and rigor, depending upon the nature of the standards that such methods would have to meet. If the standards were specific and rigorous enough, then the resulting methods may produce consistent, rigorous results. However, it seems that significant agency oversight and enforcement would be necessary to ensure sufficient consistency and rigor in practice.

[4] For example, one can imagine that DTSC would develop one method for formulated products and another for assembled products.

The second category provides substantially greater assurance of rigor, transparency and consistency than the third, and the opportunity for greater proportionality than the first.